

## To Compare the Efficacy of Pre-Operative Prophylactic Antibiotic Therapy Versus Routine Post-Operative Antibiotics in Routine Gynecological Surgeries

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### Abstract

**Background:** Cesarean section and hysterectomy are most commonly performed operations in obstetrics and gynecology. The most common complication associated with hysterectomy is infection. Single dose preoperative antibiotic prophylactic therapy also reduces cost, potential toxicity, post operative infection and risk of duration of hospitalization, colonization with resistant organisms hence, the current study is undertaken to evaluate a efficacy of single dose of preoperative antibiotic prophylaxis versus routine postoperative antibiotic therapy in gynecological surgeries. **Method:** 100 patients admitted and undergoing elective Gynecological surgeries like vaginal hysterectomy, abdominal hysterectomy and laparotomies in the department of Obstetric and Gynecology were enrolled in the study as per selection criteria. They were randomly assigned as group I and group II after obtaining informed consent. **Result:** The incidence of febrile morbidity in group I was 5% and 8.33% in group II and was statistically insignificant. Incidence of infectious febrile morbidity in group I is 1.66 and 3.33% in group II. 3.33% patients in group I and 5% patients in group II had non-specific pyrexia. The incidence of postoperative infectious morbidity in group I was 5% and in group II was 10%. Prolonged postoperative stay (>10 days)

observed in 10% of patients in group I and 21.66% patients in group II. **Conclusion:** Single dose antibiotic prophylaxis is equally effective in preventing post operative (respiratory/ urinary/ pelvic) infections and surgical site infection. As far as safety is concerned, single dose antibiotic is safer than routine antibiotic for prolonged period. Single dose antibiotic prophylaxis is more cost effective than routine antibiotic for prolonged period.

**Keywords:** Febrile Morbidity; Postoperative Stay; Antibiotic Prophylaxis; Adverse Effect of Drug.

### Introduction

Today in this rising trend of operative interventions with rise in both obstetrical and gynecological surgeries, India is experiencing a new revolution in patient management. significant patient morbidity. Postoperative infection remains the most common complication of surgical procedures in gynecology [1]. Cesarean section and hysterectomy are most commonly performed operations in obstetric and gynecology. The most common complication associated with hysterectomy is infection. The most frequent infectious complication of hysterectomy is pelvic or vaginal cuff cellulitis, pelvic cellulitis is a polymicrobial infection, predominantly with endogenous organisms that can progress to septicemia, systemic inflammatory response syndrome, pelvic abscess, septic pelvic thrombophlebitis, or septic shock.

Substantial body of evidence confirms the role of prophylactic antibiotics and the fact that prophylactic antibiotics lead to reduction in febrile morbidity and post operative

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wound infection, justifies a policy of recommending prophylactic antibiotic to women undergoing elective or emergency cesarean section and gynecological surgeries.

The prophylactic use of antibiotic for surgical procedure has become a standard practice. Studies have shown that the incidence of infections complication following abdominal and vaginal hysterectomy decreases with adequate prophylaxis to as low as 12-32% of the rate expected without preoperative antibiotic therapy.

Gynecological surgeries are classified as clean contaminated surgeries antimicrobial prophylaxis for various clean or clean contaminated surgical procedures has become standard of practice to reduce the risk of post operative infectious morbidity. Antibiotic prophylaxis has been standard practice in vaginal hysterectomies for many years. Support for prophylactic antibiotic in abdominal hysterectomies has undergone a recent meta-analysis showing its benefit.

The preoperative delivery of parental antibiotics critical period has markedly reduced the rates of post operative morbidity for a wide variety of surgical procedures.

Although prophylactic antibiotics are frequently used for minor gynecological procedures, the indication for their use in gynecology has been established only for certain procedures like vaginal and abdominal hysterectomy, high risk laparotomy, radical oncologic surgical procedures and tubal surgery.

There is always a thought of great surgeon Woodruff "antibiotics can make a third-rate surgeon a second rate one, but they can make a second-rate surgeon a first class one." [2].

Stone et al. went to demonstrate that long courses of antibiotic beyond the recovery room were not beneficial. Perioperative antimicrobial prophylaxis has long been advocated in surgical procedure, but recent guidelines and publication shown that single dose preoperative antibiotic prophylaxis are equally effective, in clean and clean contaminated surgeries if antibiotics with an adequate half life to cover for the length of the operation are used. Inappropriate and prolonged use of antibiotic is a serious problem it increases the morbidity and mortality of patients and also increase health care cost due to increased antibiotic resistance rates. Antibiotics administered prior to skin incision may further reduce the risk of postoperative infection. At the time of incision to be effective, antibiotics need to be present adequately in the tissue. Postoperative antimicrobial prophylaxis is unnecessary as it increases cost and causes drug resistance with resistant bacteria [3].

Single dose preoperative antibiotic prophylactic therapy also reduces cost, potential toxicity, post operative infection and risk of duration of hospitalization, colonization with resistant organisms hence, the current study is undertaken to evaluate a efficacy of single dose of preoperative antibiotic prophylaxis versus routine postoperative antibiotic therapy in gynecological surgeries.

#### *Aims*

To compare the efficacy of pre-operative prophylactic antibiotic therapy versus routine post-operative antibiotics in routine gynecological surgeries.

#### **Material and Methods**

The present study prospective randomized clinical controlled trial design was conducted at Department of Obstetrics and Gynecology. During the study period, 100 patients admitted and undergoing elective Gynecological surgeries like vaginal hysterectomy, abdominal hysterectomy and laparotomies in the department of Obstetric and Gynecology were enrolled in the study as per selection criteria. They were randomly assigned as group I and group II after obtaining informed consent.

#### *Inclusion Criteria*

All patients undergoing major gynecological surgeries for various indications.

#### *Exclusion Criteria*

Patient excluded from study those having known hepatic and renal insufficiencies, Suspected or known hypersensitivity to cephalosporins, any preexisting infection in the patient.

*Group I:* 50 cases received single dose third generation cephalosporin injection cefotaxime 2gm IV 30 minutes prior to incision.

*Group II:* 50 patients received routine postoperative antibiotic treatment for 7 days. Group II were given inj. ciprofloxacin 200mg IV 12 hourly plus inj. metronidazole 500mg 8 hourly for 24 hourly followed by the oral tab. Ciprofloxacin 500mg 12 hourly plus tab metronidazole 400 mg 8 hourly for next 6 days.

Assessment was performed that included measurement of vital signs (plus rate, respiratory rate, blood pressure and body temperature), general physical, systemic and gynecological examinations.

Routine preoperative investigations are done. Routine preoperative care including, skin preparation, soap enema the evening before surgery, a povidone iodine scrub and shaving of surgical area, were performed for all patients.

Cefotaxime (3<sup>rd</sup> generation cephalosporin) was used for prophylaxis, because it is effective against wide range of pathogens and less adverse effect and adequate half life and effective in preventing postoperative gynecological infection.

During postoperative period of hospitalization records of 4 hourly temperature was maintained along with other vital signs, abdominal, perineal examinations were performed daily. If body temperature was greater than 38°C then patients were assessed for signs and symptoms of infection. If there was evidence of primary infection then appropriate investigations were sent before initiating antimicrobial therapy. The blood and urine examination were performed on third day after surgery. If patients had febrile morbidity with underlying infection, additional investigation like wound swab for culture sensitivity and blood culture were done. Wound was inspected for superficial or deep infection, pus discharge, abscess formation, wound dehiscence, vault hematoma and pelvic abscess. Patients were also assessed for respiratory or urinary tract infection. At discharge, patients were instructed to contact if they experience signs and symptoms of infection. All patients were monitored for 45 days post operatively.

Study medication was given intravenously at the time of 30 minutes prior to skin incision. In case of extensive blood loss (>1500ml) or surgical duration longer than 2-3 hours, second dose of antibiotic was administered. Surgery was performed by gynecologists and senior residents. In women who underwent vaginal hysterectomy for prolapsed the catheter was retained for three days. After surgery, each patient was assessed daily until they were discharged from the hospital in postoperative period for evaluation of infectious morbidity and tolerability. The main outcome measures of study were febrile morbidity and postoperative infectious morbidity.

Infection included abdominal wound infection, pelvic cellulitis, vaginal cuff infection, or urinary tract infection (both symptomatic and asymptomatic). Pelvic cellulitis, was diagnosed by the triad of increasing lower abdominal discomfort, temperature elevation and increasing tenderness to gentle deep lower abdominal palpation.

### *Statistical Analysis*

The values are expressed as mean±standard deviation or percentages. Demographic data and baseline patient characteristics were analyzed by Student's t-test for difference between means or proportions. Data regarding post operative infectious morbidity was analyzed by Z-test for proportions, Fisher's exact test for small sample and Chi-square test, p value <0.05 was considered statistically significant.

### **Results**

The differences in the means of age, weight, BMI and haemoglobin between two groups were not statistically significant ( $p>0.05$ ). Hence two groups were comparable (Table 1).

In the present study, total abdominal hysterectomy was done on 30 patients, (15) 30% in each group, vaginal hysterectomy on 2 patients (1) 3.33% in each group, vaginal hysterectomy with anterior colporrhaphy or posterior colporrhaphy done on 54 patients, (28) 56% in group I and (26) 52% in group II, out of 12 patients (5) 10% in group I and (7) 14% in group II exploratory laprotomies and (2) 2.0% other surgeries were performed. Hence vaginal hysterectomy with anterior colporrhaphy and posterior colporrhaphy (54%) was the most common gynecological surgery in study of surgery in both groups was statistically not significantly distributed ( $p=0.8$ ), Hence they were comparable (Table 2).

Patients with febrile morbidity were (3) 6% in group I and (5) 10% in group II. On comparison between groups, it was found that difference is statistically not significant ( $p=0.72$ ).

Noninfectious febrile morbidity was (2) 4% in group I and (3) 6% in group II. On comparison between groups, it was found that difference is statistically not significant ( $p=0.99$ ).

Infectious febrile morbidity was (1) 2% in group I and (2) 4% in group II. On comparison between groups, it was found that difference is statistically not significant ( $p=0.62$ ) (Table 3).

In the present study, 3 (6%) of patients in group I developed postoperative infectious morbidity compared to 12% patients in group II. Out of that one patient had burst abdomen in group I. One patient had vault infection after vaginal hysterectomy and one patient had urinary tract infection in group I. In group II, out of (5) 12% patients, 2 patients had vaginal cuff cellulitis, 1 patient had vault infection,

2 patients had wound gape and one had urinary tract infection. This is supported by microbiological examination of smears from respective sites.

One patient from each group developed vault infection, and urinary tract infection, two patients from group II developed vaginal vault cellulitis and patients developed wound gape. No patient had respiratory tract infection in either group (Table 4).

Only minor suspected adverse drug effects like nausea, headache, vomiting and dizziness were reported by 3% women in group I and 11.66% in group II. On comparison between groups, it was

found that difference is statistically not significant (p=0.16) (Table 5).

The mean postoperative stay in group I was 7.61± 3.76 days and 10.1± 5.52 days in group II. The hospital stay statistically significant more in group II than group I (p=0.009).

### Discussion

Post operative infection remains the main cause of morbidity in gynecological surgery. The reported

**Table 1:** Baseline characteristics

Parameters	Group I		Group II		P value
	Mean	SD	Mean	SD	
Age (years)	44.31	11.9	45.8	10.1	0.50
Weight (Kg)	54.76	6.4	54.31	6.9	0.74
BMI (kg/m <sup>2</sup> )	22.77	2.3	22.82	2.4	0.92
Hb (gm%)	9.07	0.66	9.16	0.68	0.50

**Table 2:** Distribution of patients according to type of surgery

Type of Surgery	Group I		Group II	
	Frequency	Percentage	Frequency	Percentage
Abdominal hysterectomy	15	30.0	15	30.0
Vaginal Hysterectomy	1	2.0	1	2.0
Vaginal Hysterectomy + Anterior colporrhaphy or posterior colpoperineorrhaphy	28	56.0	26	52.0
Exploratory laparotomy	5	10.0	7	14.0
Others	1	2.0	1	2.0

**Table 3:** Post operative incidence

Incidence	Group I (n=50)		Group II (n=50)		p-value
	Frequency	Percentage	Frequency	Percentage	
Febrile morbidity	3	6.0	5	10.0	0.72
Noninfectious febrile morbidity	2	4.0	3	6.0	0.99
infectious febrile morbidity	1	2.0	2	4.0	0.62

Fisher's exact test

**Table 4:** Incidence of post operative Infectious morbidity

Sr. No.	Type of infection	Group I (n=50)	Group II (n=50)
1	Superficial infection	-	-
2	Deep infection	-	-
3	Wound dehiscence	1	2
4	Vault hematoma	0	0
5	Vault cellulitis	-	2
6	Vault infection	1	1
7	Pelvic abscess	0	0
8	UTI	1	1
9	RTI	0	0
	Total	3 (6%)	6 (12%)

**Table 5:** Tolerability of drug

Suspected adverse effect of drug and other side effects	Group I (n=50)	Group II (n=50)
Nausea ± vomiting	1	6
Headache ± dizziness	1	1
Total	2 (4%)	7 (14%)

Fisher's exact test

**Table 6:** Post operative hospital stay (mean ± SD)

Group I	Group II	P value
7.61 ± 3.76 days	10.1 ± 5.52 days	0.009

incidence of surgical site infection leading to longer hospital stay and increased cost is up to 5% [4].

The frequency of post operative infection has been reported to high without use of antibiotic prophylaxis. Short course of prophylactic antibiotic is as efficacious as longer course in preventing post operative infection. Many studies have proved the efficacy of antibiotic prophylaxis in preventing surgical site infection. Single dose prophylaxis can help in the reduction of medical cost and development of micro-organism resistance [5,6,7].

No intra-operative surgical complication was observed. Extra dose of intra-operative dose of inj. cefotaxime given in 3 patients, when surgery was prolonged for more than 2hrs. Recently, another aspect of prophylaxis is to shorten the duration of antibiotic use. For most hysterectomies, a single dose of antibiotic is sufficient [8]. Current information suggests that additional dose should be given at intervals of twice the half-life of the antibiotic to maintain adequate levels throughout the procedure [9].

Regarding postoperative complication, total febrile morbidity is 8% in our study, and 6% in group I and 10% in group II.

Among them, only three patients had underlying infectious febrile morbidity irrespective of Hb level. Out of three patients, one patient (2%) in group I had febrile morbidity and cause being deep wound infection in a case of abdominal hysterectomy. Two patients (4%) in group II had febrile morbidity and cause being vault cellulitis in postoperative case of a vaginal hysterectomy, which was confirmed by microbiological examination of smears from the infection sites.

The incidence of febrile morbidity in the hysterectomy group was 10% in Chongsomchai et al. [10] study. Multiple studies have evaluated the incidence of postoperative febrile morbidity after major gynecologic surgeries, with rates of 32-52% [11,12]. In present study the incidence of postoperative febrile morbidity is shown less than the above studies.

MC Nally et al. [13] also showed postoperative fever in the first 72 hours after major gynecologic surgery was common and nonspecific, and require no treatment. Even routine laboratory studies were not recommended if the patients did not show any other signs of symptoms of infection.

The incidence of febrile morbidity in group I and group II is statistically not significant. Hence single dose antibiotic prophylaxis is as efficacious as routine antibiotic for prolonged period.

Tanos V [14], in his study used single dose antibiotic prophylaxis and found reduced febrile morbidity ( $p < 0.001$ ).

Studies have shown that the incidence of infectious complications following abdominal and vaginal hysterectomy decreases with adequate prophylaxis to as low 12-32% of the rate expected without preoperative antibiotic therapy [15]. In the present study, the incidence of postoperative infection was 6% in group I and 12% in group II.

In a single dose preoperative group, one patient had burst abdomen on postoperative day nine and purulent discharge from the wound and fever. Culture sensitivity reports came positive for *Citrobacter* species and *Klebsiella oxytoca*, and treated with parental antibiotics. Resuturing was done. One patient had superficial vault infection, and culture reports came positive for *E.coli* and *Klebsiella arogenes* and treated the parental antibiotics.

In the routine antibiotic group, 3 patients had wound dehiscence. One patient had non-infected gape, culture reports came sterile and probably due to obesity. Other 2 patients had infective wound gape, culture reports positive for organisms like MRSA, coagulase positive *Staphylococcus aureus* and resuturing was done.

Two patients in routine antibiotic group had vault cellulitis and culture reports came positive for *Staphylococcus aureus* and MRSA (Methicillin Resistant *Staphylococcus Aureus*) and responded to parental antibiotics. One patient in each group had

urinary tract infection and urine culture report came positive for Coagulase negative Staphylococcus aureus and E.coli respectively, none of patients in both groups detected respiratory tract infection.

The factors like Hb% and nutritional status have marked influence on postoperative infection, which was observed in earlier study.

Postoperative infection is not only dependent on antibiotic use but also on many other factors, such as also age, nutritional status, hygienic condition, anaemic status, duration of operative procedure, suture material, blood loss.

Nissa M [16] has shown 5% wound infection in their study. Broodt J.P [17](1990), reported reduction in the number of urinary tract infection in his study with single dose regimen.

The postoperative hospital stay is significantly less in a single dose antibiotic group than the routine antibiotic group. Because of postoperative infectious morbidity and wound gape, nine patients had prolonged postoperative stay.

One patient had readmission for vault cellulitis and treated with parental antibiotics had prolonged hospital stay in present study. Every patient receiving routine antibiotic group stays for 7 days before discharge but patients receiving single dose prophylaxis can be discharged earlier two days after surgery, hence operative stay is less in group I.

Single dose offers patient compliance. 14% patients of routine antibiotic group complaint of many side effects, like nausea, vomiting, dizziness, etc. while only 4% patients in single dose group complaints nausea, headache and other adverse effects. Most of complaints were due to use of metronidazole, no significant difference was found in two groups. Hence single dose antibiotic is safer than routine antibiotic for 7 days.

A study conducted by Her Yount [18] has shown that single dose of antibiotic prophylaxis can reduce the antibiotic cost by 75-80%.

Addition cost savings were also found and were related to decrease resistance organism outbreak, decreased postoperative wound infection, decrease length of hospital stay, readmission, related surgeries and re-treatments.

Tchabo JG [19], was reported non-significant difference in the incidence of post operative and mean duration of hospital stay, when comparing single dose versus antibiotic dose.

The results of present study were as similar as our study expect hospital stay is significantly less in

single dose group than routine antibiotic group in present study.

The Cormio G. [20] conducted a prospective randomized study comparing amoxicillin clavulanic acid with cefazolin shows that single dose regimen also resulted in an obvious reduction the cost of antibiotic used, without an increase in morbidity. The results were similar in present study.

The Itskovitz J [21], was conducted in his study that short course of prophylaxis effectively decreases the febrile morbidity, serious postoperative infection and hospital stay. The results were similar in present study.

Results of a series of three double blind controlled clinical studies by MC Gregor JA [5] has shown that single dose ceftizoxime was as effective as adjunctive chemotherapy in patients at risk of postoperative infection after hysterectomy.

Our study signifies that single dose preoperative antibiotic prophylaxis can be effectively used in our institution as compared to routine post operative antibiotic for prolonged period in gynecological surgeries.

## Conclusion

The present study was just an initiative to develop acceptability among the prescribers to use optimal antimicrobial prophylaxis in gynecological procedures. Single dose antibiotic prophylaxis is equally effective in preventing post operative (respiratory/ urinary/ pelvic) infections and surgical site infection. Single dose antibiotic prophylaxis is more cost effective than routine antibiotic for prolonged period.

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